K123394 page 1/2

510(k) Summary

JUN 0 6 2013

Submitted by:	Coreleader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 FAX: +886-2-26968882
Contact Person:	Niko Wei
Date Prepared:	Jan 24, 2013
Proprietary Name:	Coreleader Hydro-clear Hydrocolloid Wound Dressing
Common Name:	Hydrocolloid Wound Dressing
Classification:	Unclassified
Classification Name:	Topical Wound Dressing Pad
Predicate Device:	3M™ Tegasorb™ Hydrocolloid Dressings
Device Description:	Coreleader Hydro-clear is a new product that is made of Hydrocolloid (Sodium carboxymethyl cellulose, Synthetic Elastomer, Tackifier Resins, Mineral Oil and Polyurethane film) by unique production process. With preferable liquid absorbsion ability, gas permeability and ability of water resistant, Hydro-clear is clear of adhesive onto wound, capable to absorb exudates, protect wound site and facilitates would healing process.
Intended Use:	Coreleader Hydro-clear is indicted for the management of 1st and 2nd degree burns, chronic ulcers, surgical wounds, skin graft and donor sites. Patient with conditions listed below is considered appropriate for Over-The Counter Use (OTC): for the management of minor cuts, minor burns (1st degree burns), minor lacerations and minor cuts.

Technological Characteristics:

Thickness	0.5 mm
Peeling Adhesion	687 g/25 mm
Holding Power	140 min/onch
Elongation	235 %
Tensile Strength	2360 g/25 mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 6, 2013

Coreleader Biotech Co., Ltd.
% Mr. Niko Wei
Regulatory Affair Officer
19F, No. 100, Sec. 1,
Xntai 5th Road, Xizhi District
New Taipei City, Taiwan, R.O.C. 22102

Re: K123394
Trade/Device Name: Coreleader Hydro-Clear Hydrocolloid Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 17, 2013
Received: May 03, 2013

Dear Mr. Wei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123394

Device Name: Coreleader Hydro-clear Hydrocolloid Wound Dressing

Indications for Use:

Coreleader Hydro-clear is indicted for the management of 1st and 2nd degree burns, chronic ulcers, surgical wounds, skin graft and donor sites.

Patient with conditions listed below is considered appropriate for Over-The Counter Use (OTC): for the management of minor cuts, minor burns (1st degree burns), minor lacerations and minor cuts.

Prescription Use ___V___ AND/OR Over-The-Counter Use ___V___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123394